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Jodi M. Finder

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ARTICLE

THE FUTURE OF PRACTICE GUIDELINES: SHOULD THEY CONSTITUTE CONCLUSIVE EVIDENCE OF THE STANDARD OF CARE?

Jodi M. Finder[†]

I. INTRODUCTION

THE CONSISTENT USE OF WELL-DEVELOPED and medically appropriate practice guidelines has two potentially compelling benefits. First, scientifically reliable guidelines can improve medical practice by reducing the incidence of misdiagnoses and inappropriate treatment decisions. Particularly when they delineate national standards of care, guidelines can improve the consistency with which particular procedures are chosen and applied to particular diagnoses. In addition, they can improve clinical outcomes and promote the efficient use of resources in a health care system dominated by managed care rationing.

Second, if major inroads are made into the process of creating and disseminating guidelines, their use may improve the process of malpractice litigation when the practice of medicine goes awry or when insurance coverage is denied. Plaintiffs already rely on guidelines in attempting to prove that a defending physician, hospital, or other health care provider deviated from the standard of care. In contrast, defendants seek to introduce

[†] LL.M., 1999, The George Washington University Law School; J.D., 1998, The George Washington University Law School; B.A., *cum laude*, 1995, Duke University. Ms. Finder is currently an associate in the Washington, D.C. office of Greenberg Traurig, LLP.

guidelines to demonstrate that their actions or judgments were consistent with the applicable standard of care.

The legal and medical professions are currently debating the value of practice guidelines as conclusive evidence of the standard of care in both individual coverage and professional liability cases. Nationally accepted guidelines can help streamline the judicial process by providing courts and juries with clear standards against which to measure a provider's behavior in practicing medicine. However, given the legitimate variation in what procedures are considered appropriate for certain diagnoses and the need for physicians to exercise independent medical judgment in cases where variables preclude simple solutions, guidelines may have only limited utility in the legal process. As J. Rosser Matthews proffers:

[E]ven though the introduction of practice guidelines may promote the policy objective of cost-effectiveness in the delivery of health care services, their use to establish culpability in actual cases may be more difficult because the structure of legal reasoning focuses on the particular facts in the case at hand rather than appealing to abstract decision procedures.¹

Although the use of guidelines in practice presents a promising solution for improving care and rationalizing the use of health care products and services, this does not provide an unambiguous strategy for reducing the number of "bad" decisions or outcomes.² Persistent commitment on the part of practitioners and policy makers towards developing and disseminating guidelines through rigorous methods is crucial to their future success.³

As discussed *infra*, the Tenth Circuit's surprising deference to a plan's reliance on its administrator's own guidelines in denying coverage prospectively, thereby essentially making a medical decision to deny access to coverage, casts doubt on the

¹ J. Rosser Matthews, *Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish*, 24 J. HEALTH POL., POL'Y & L. 275, 275 (1999) (discussing the potential difficulties of using practice guidelines in the adjudication of malpractice).

² See COMMITTEE ON CLINICAL PRACTICE GUIDELINES, INSTITUTE OF MEDICINE, *GUIDELINES FOR CLINICAL PRACTICE: FROM DEVELOPMENT TO USE* 39 (Marilyn J. Field & Kathleen N. Lohr eds., 1992) [hereinafter IOM I].

³ See *id.*

possibility that the courts will condition the evidentiary weight of guidelines on their success in the peer review process and acceptance by nationally accredited bodies. Due to this seemingly blind approval by one region of the federal judiciary, the future of guidelines remains uncertain. Their potential to improve both the practice of medicine and the legal process when that practice fails is tremendous. However, even if a national body is ordained as the ultimate arbiter of which guidelines are deemed "gold standards," a physician should neither be deemed per se negligent simply for departing from a guideline's recommendations nor be deemed innocent simply for adhering to them. In light of the fact that issues arise regarding the appropriateness of guidelines as the standard of care for one particular patient, not only is it not desirable for guidelines to be deemed conclusive, it is not remotely possible in practical terms.

Although the controversy surrounding the use of guidelines in insurance coverage decisions is timely and fascinating and will be addressed, the focus of this Article is the use of guidelines as evidence in malpractice litigation. This Article argues that guidelines have valuable utility in ascertaining the applicable standard of care in malpractice cases, but they should not be given conclusive weight. Part II defines the array of practice guidelines, their applications, and their commonalities. Part III explains the process of admitting guidelines into evidence to prove or disprove malpractice. Part IV asserts the continued need for a judicial process through which the guidelines themselves can be challenged. Part V surveys how various courts have approached the admissibility of guidelines. Part VI explores judicial and legislative attempts at affording them conclusive weight. Part VII evaluates how guidelines could improve the process of malpractice litigation. Finally, part VIII acknowledges the biases inherent in using them for evidentiary purposes.

II. DEFINING PRACTICE GUIDELINES

A legal and policy exploration of practice guidelines requires a basic understanding of their composition, both in form and substance. This section addresses the range of definitions and applications.

A. Medical Application of Practice Guidelines

Also referred to as "clinical algorithms," "critical pathways," "clinical practice protocols," and "practice parameters," the term "practice guidelines" encompasses a range of functions and formats.⁴ The Institute of Medicine (IOM) defines guidelines as "systematically developed statements to assist in practitioner and patient decisions about appropriate health care for specific clinical circumstances."⁵ "[G]uidelines are intended to assist practitioners and patients in making health care decisions . . . [and] to serve as a foundation for instruments to evaluate practitioner and health system performance."⁶

Practice guidelines serve various substantive functions. They provide guidance on the use of medical devices, criteria for prescribing pharmaceuticals, and recommendations for treating specific ailments.⁷ Regardless of their format, they are aimed at promoting both higher quality and more cost-effective health care by making the clinical knowledge generated through outcomes research available and more easily accessible.⁸ Representatives of all parties in the health care continuum hope that use of guidelines will improve the quality of care, as well as ameliorate the "perceived value obtained for health care spending. Beyond such widely held aspirations, individual groups differ in the emphasis they place on other narrower objectives."⁹ Regulators, administrators, and purchasers are interested in controlling cost and decreasing variation in practice patterns.¹⁰ Practitioner groups seek to maintain professional autonomy to free medical decision-makers from engaging in "external

⁴ This Article refers to two labels, practice guidelines (or guidelines) and protocols. For purposes of the topics discussed herein, the two terms are used interchangeably.

⁵ COMMITTEE TO ADVISE THE PUBLIC HEALTH SERVICE ON CLINICAL PRACTICE GUIDELINES, INSTITUTE OF MEDICINE, *CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM*, at 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990) [hereinafter IOM II].

⁶ *Id.* at 2-3.

⁷ See Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?*, 266 JAMA 2856, 2856 (1991) (stating that practice guidelines are expected to change practice styles, reduce inappropriate and unnecessary care, and cut costs).

⁸ See Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 370 (1995) (reviewing the development of clinical practice guidelines and their impact on the health care reform debate).

⁹ See IOM I, *supra* note 2, at 23.

¹⁰ See *id.*

micromanagement.”¹¹ Advocates of patient rights perceive guidelines as a means of informing patient decisions, clarifying their preferences, and improving patient autonomy.¹²

In their ideal form, guidelines provide a framework for medical decision-making. As defined by IOM, they have “one crucial purpose: to assist individual practitioners and patients in making decisions about specific clinical problems.”¹³ They provide recommendations for managing a patient’s care that identify a management strategy or a range of strategies¹⁴ reflecting informed judgment on how to treat a particular medical condition.¹⁵ Individuals and organizations use guidelines “to structure organizational procedures, to guide equipment purchases and hiring decisions, and to set and implement priorities for monitoring, feedback, and other efforts to assess and improve performance.”¹⁶

Physicians have come to rely significantly on practice guidelines, tending to prefer them over other resources. One study asked medical directors to rank the sources of information used in their decision-making processes.¹⁷ The choices included medical journals, expert opinions, Food and Drug Administration (FDA) documents, practice guidelines, Medicare policies, National Institute of Health (NIH) conferences, and practices of other plans.¹⁸ Whereas less than sixty percent of those surveyed considered medical journals to be an optimal source of guidance and forty percent or less considered other sources optimal, use of practice guidelines was ranked ahead of national expert information, government documents, and NIH conferences.¹⁹

¹¹ *Id.*

¹² *Id.*

¹³ *Id.* at 40.

¹⁴ See Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556 (1990).

¹⁵ See Rosoff, *supra* note 8, at 370.

¹⁶ IOM I, *supra* note 2, at 41.

¹⁷ See Claudia A. Steiner et al., *The Review Process Used By U.S. Health Care Plans to Evaluate New Medical Technology for Coverage*, 11 J. GEN. INTERNAL MED., at 294 (1996) (concluding that no one source of information was definitive).

¹⁸ Sara Rosenbaum et al., *Who Should Determine When Health Care is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 231 (1999) (citing Steiner et al., *supra* note 17, at 294-302).

¹⁹ See *id.*

B. The Development of Practice Guidelines

1. Sources of Practice Guidelines Development

For decades, public and private medical associations, as well as non-medical bodies, have created practice guidelines through a variety of approaches. They vary substantially in authorship, form, dissemination, and purpose. Some guidelines are developed by specialty associations, such as the American Academy of Pediatrics. Others are developed purely through actuarial methods, such as those created by Milliman and Robertson. At another end of the continuum are protocols that have undergone extensive peer review by practitioners. Societies, such as the American Academy of Pediatrics, the government through NIH, and hospitals have been at the forefront of the guidelines trend.²⁰ According to General Accounting Office estimates, approximately seventy-five organizations have developed more than 2000 guidelines.²¹ In fact, so many have been written that the Agency for Health Care Policy and Research, along with the American Association of Health Plans (AAHP) and the American Medical Association (AMA), created a National Guideline Clearinghouse (NGC) on the Internet.²²

2. Establishment of the Agency for Health Care Policy and Research

In November, 1989, Congress amended the Public Health Service Act to establish the Agency for Health Care Policy and Research (AHCPR) as an independent agency.²³ The legislation requires that a program be instituted "[f]or the purpose of promoting the quality, appropriateness, and effectiveness of health care," and has resulted in the creation of the AHCPR's Forum for Quality and Effectiveness in Health Care (the Forum).²⁴

²⁰ See BARRY R. FURROW ET AL., *HEALTH LAW* 365 (1995) (citing origins of practice guidelines and anticipated benefits and harms).

²¹ See *Practice Guidelines: Managed Care Plans Customize Guidelines to Meet Local Interests* GAO-HEHS-96-95, (May 30, 1996), at 3 (discussing the purpose of clinical practice guidelines and their current use within health plans).

²² See AHCPR, National Guideline Clearinghouse (visited July 14, 2000) <<http://www.guideline.gov/index.asp>>. See also Mark Crane, *Clinical Guidelines: A Malpractice Safety Net?*, MED. ECON., Apr. 12, 1999, at 236, 239 (adding that many of these clinical guidelines contradict one another).

²³ See 42 U.S.C. § 299b-1(a) (1994); Pub. L. No. 101-239 (1990).

²⁴ 42 U.S.C. § 299b-1(a) (1994).

More specifically, the AHCPR is charged with the responsibility of supporting research, gathering data, and other activities:

[T]o arrange for the development and periodic review and updating of – (1) clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and (2) standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.²⁵

Pursuant to a request for advice on how the agency should approach its responsibility for guidelines, the IOM appointed a study committee to provide technical help in developing good guidelines.²⁶ Evaluations have revealed that the AHCPR has faced a daunting task in improving the quality of medicine nationwide. Given the newness of the program and a pattern of significant staff turnover, the agency has found itself “in flux.”²⁷ The magnitude of the responsibility imposed on the guidelines panel chairpersons was more demanding than initially envisioned, the literature reviews were more costly in terms of time and money than expected, and explicit instructions regarding methodology were lacking. Contracting with other organizations was part of the agency’s response to these difficulties.²⁸ In 1991, it began to expand its reach by awarding contracts for the creation of three sets of protocols: (1) to the American Academy of Pediatrics (with subcontracts to the American Academy of Family Practice, the American Academy of Otolaryngology, and the Children’s Hospital of Pittsburgh) for otitis media in children; (2) to the RAND Corporation for congestive heart failure and post-stroke rehabilitation; and (3) to the Center for Health Economics Research (with a subcontract to the Harvard School of Public Health) for a literature analysis and review.²⁹ Although the contracting approach has

²⁵ *Id.*

²⁶ See IOM II, *supra* note 5, at 1.

²⁷ See IOM I, *supra* note 2, at 165.

²⁸ See 42 U.S.C. § 299b-1(c) (1994).

²⁹ See IOM I, *supra* note 2, at 56.

left AHCPR out of direct involvement in reviewing the literature and scientific evidence, the Forum expected to exercise substantial oversight over the panels, work plans, and literary reports,³⁰ thereby reducing the risk that the specialty organizations would lack impartiality in the process.

C. Beyond the Medical Use of Practice Guidelines

On a purely medical plane, practice guidelines and their purported utility are straightforward and uncontroversial. However, medicine is no longer defined in purely curative terms. The inescapable reality is that the practice of medicine is largely governed and often hampered by coverage, cost, and regulatory requirements. Furthermore, interest in practice guidelines on the part of the multiple players in the American health care system has increased in light of the dominance of managed care, which allows plans to maintain control over providers.³¹ Because, by definition, managed care organizations (MCOs) control financial output to providers, they also profoundly influence the medical decision-making process.

Contracts between MCOs, including health maintenance organizations (HMOs), and physicians generally include clauses that vest discretion in the MCO to prospectively decide when a particular treatment or procedure is medically necessary and, therefore, whether it will be covered.³² Most MCOs and some physician practice organizations employ practice guidelines to curb costs in expensive areas, such as asthma management.³³ The majority of insurance purchasers are companies that procure coverage for employees who, in turn, are reluctant to accept increases in premiums. The employers advocate that the health care delivery system institute utilization management systems out of the belief that quality of care will improve as a result of more consistent practice patterns, thereby yielding lower costs by reducing coverage of unnecessary and redundant services.³⁴ These customers are insisting that practitioners be

³⁰ See *id.*

³¹ See RAND E. ROSENBLATT ET AL., *LAW AND THE AMERICAN HEALTH CARE SYSTEM* 568 (1997).

³² See *id.*

³³ See *id.*

³⁴ See Marlene Travis & Sue Ellen Bell, *Strategies for Managing Medical Risks in Managed Care Organizations*, in *GUIDE TO MANAGED CARE STRATEGIES* 199 119, 120 (Joseph Burns et al. eds., 1998) (discussing the possibility of reducing health care

held increasingly accountable for the level of care delivered to patients.³⁵

In the bureaucratic and contentious environment in which MCOs have come to operate, denial of care by insurers and poor outcomes by providers have spurred a culture of aggravated and adversarial battles – patients are demanding accountability. Guidelines perhaps stir up the most controversy when used in the process of litigating coverage and quality of care disputes. It is interesting that the NGC website noted previously enumerates a purely medical group of players as its “intended audience,” including health care providers and provider organizations, medical specialty and professional societies, researchers, policy makers, and employee benefits managers.³⁶ However, it fails to mention lawyers and judges.³⁷ It also explicitly refuses to make:

[W]arranties concerning the content or clinical efficacy of the clinical practice guidelines and related materials. Inclusion of any guideline in the NGC does not constitute or imply an endorsement by the AHCPR or its contractor[s] . . . of the guidelines or of the sponsor or developer of any such guidelines.³⁸

In fact, virtually all guidelines contain disclaimers that the recommendations contained therein are not intended to be deemed “the standard of care.”³⁹ It appears that guideline creators intentionally avoid this kind of explicit endorsement due to concerns over potential liability.

III. UTILITY OF GUIDELINES IN PROVING AND DEFENDING MALPRACTICE

Coverage denials are a high-profile source of litigation, and practice guidelines are implicated in such cases because they provide the basis for insurance coverage decisions. However,

costs in managed care organizations through adoption of a quality care management process).

³⁵ See *id.*

³⁶ See AHCPR, National Guideline Clearinghouse, *supra* note 22 (identifying the intended audience of the website).

³⁷ See *id.*

³⁸ *Id.*

³⁹ Crane, *supra* note 22, at 240 (noting that virtually all drafters of guidelines disclaim their recommendations as standards of care).

the following discussion focuses on their use in the malpractice context.

A. The Plaintiff's Burden in a Malpractice Action

The significance of the role practice guidelines can, and already do, play in malpractice litigation becomes apparent when considered in the context of what an aggrieved party must show to establish a cause of action. The plaintiff must prove four elements to establish a *prima facie* case of negligence: (1) the defendant owed the plaintiff a duty to conform his or her conduct with a standard of care necessary to avoid an unreasonable risk of harm to others; (2) the defendant's conduct, by act or omission, did not comport with the applicable standard of care; (3) the defendant's failure to satisfy the standard of care was causally related to the harm suffered by the plaintiff; and (4) the plaintiff actually suffered harm.⁴⁰

The second and third prongs are central to malpractice cases involving practice guidelines, which "speak directly to the question of the standard of care."⁴¹ More specifically, in a medical malpractice case, the plaintiff must prove that the defendant health care provider deviated from an accepted standard of care, and that this abrogation caused physical harm to the plaintiff. At the heart of the debate over the use of practice guidelines in malpractice litigation is whether guidelines can provide conclusive evidence of the standard of care against which the conduct of individual practitioners is measured, or whether a plaintiff can use them to show the existence of alternative courses of treatment that the defending physician should have taken.

In *Washington v. Washington Hospital Center*,⁴² a family brought a medical malpractice action on behalf of its incapacitated daughter/wife/mother, claiming the hospital negligently failed to provide the treating anesthesiologists with a capnograph or end-tidal carbon dioxide monitor that would have allowed early detection of insufficient oxygen and, therefore, would have prevented the brain injury that ensued from an

⁴⁰ See RESTATEMENT (SECOND) OF TORTS § 328A (1965).

⁴¹ Matthews, *supra* note 1, at 289 (emphasizing that litigation highlights the conflict between the impersonal objectivity of the guidelines and the physician's personal expertise).

⁴² 579 A.2d 177 (D.C. 1990) (discussing standards of care applied to hospitals in tort actions).

abortion and tubal ligation.⁴³ The plaintiff's expert testified that the American Association of Anesthesiology Standards for Basis Intra-Operative Monitoring "encouraged the use of monitors."⁴⁴ The District of Columbia Court of Appeals ruled that the evidence presented could have led a reasonable juror to find that the prevailing standard of care as of the time of the injury required the hospital to provide the aforementioned monitors; thus, the trial judge did not err in denying the motion for judgement as a matter of law.⁴⁵ Although the *Washington Hospital Center* court did not explicitly accept the guidelines as conclusive evidence of the standard of care, this case illustrates the significant role guidelines play in the outcome of a malpractice action.

B. Ascertaining the Standard of Care in a Malpractice Action

1. Sources of the Standard of Care

The standard of care applicable in a medical tort case is not usually gleaned from external authorities, such as agency standards.⁴⁶ Rather, standards are generated through the complex interaction of leaders, professional journals and conferences, and professional networks.⁴⁷ In contrast to other industries that have relied on governmental agencies to promulgate standards, neither the Department of Health and Human Services (HHS) nor NIH nor state professional licensing boards have played major roles in the contouring of the practice of medicine.⁴⁸ Instead, over time, hundreds of comments merge to form a clinical policy; if this becomes generally accepted, then it rises to the level of "standard practice."⁴⁹

⁴³ See *id.* at 180 (explaining the hospital's failure to meet the standard of care by failing to use a carbon dioxide monitor provided a basis for a medical malpractice lawsuit).

⁴⁴ See *id.* at 82 (discussing foundation for testimony given by the plaintiff's expert on the use of monitors as a standard of care).

⁴⁵ See *id.*

⁴⁶ See FURROW ET AL., *supra* note 20, at 362 (explaining standards of care emanating from professional interactions, journal articles, and networking).

⁴⁷ See *id.*

⁴⁸ See *id.*

⁴⁹ See generally David M. Eddy, *Clinical Policies and the Quality of Clinical Practice*, 307 NEW ENG. J. MED. 343 (1982) (discussing the origins and effectiveness of clinical policies).

To date, no single authoritative set of practice guidelines exists. However, many protocols have been published, reflecting policies that have become standard in certain medical communities. The foundation for the debate over the appropriate application of practice guidelines in malpractice litigation is the fact that the "standard of care" itself is not a foregone conclusion in the American judicial system. Because human variation precludes the development of a predetermined standard for every possible situation, the jury determines the precise level of care that should be relied upon in adjudicating a particular set of facts by weighing rivaling evidence.⁵⁰ Each side of the controversy introduces evidence to support its factual and legal theories in the form of testimony by expert witnesses and the presentation of scientific studies and data.

2. The Reasonably Prudent Physician Standard

It is well-established that the baseline for establishing the standard of care in any tort case is the "reasonably prudent person standard." If the defendant fails to exercise the degree of care and prudence necessary to avoid injuring the plaintiff as a reasonable person in similar circumstances would have, then he or she is negligent.⁵¹

In cases involving defendants acting as professionals, narrower standards are derived from this gauge. A reasonable professional is expected to act in accordance with superior skills or knowledge that person holds,⁵² such as medical expertise. Where physicians are involved, a judge may elevate this standard to yet a higher level – that of a reasonably prudent medical specialist. For example, an oncologist may be compared with other oncologists or an internist compared with other internists practicing in the same geographic region.⁵³ Although the judge defines the process of ascertaining standards by ruling what forms of evidence are permissible, the jury ultimately decides the specific standard of care that should apply in a particular case.⁵⁴

⁵⁰ See Hirshfeld, *supra* note 14, at 1556 (explaining that a jury would weigh the practice parameters like any other evidence at trial).

⁵¹ See *id.*

⁵² See *id.*

⁵³ See *id.*

⁵⁴ See *id.*

C. Admission of Scientific Expert testimony

1. The *Daubert* Standard

The debate over the admissibility of practice guidelines into evidence is underscored by the shift in judicial policy on the admissibility of scientific expert testimony in general. Since 1923, *Frye v. United States*⁵⁵ had been the leading authority on the admissibility of scientific expert testimony.⁵⁶ Under *Frye*, scientific expert testimony was deemed admissible where the source from which the proffered principle was deduced had gained "general acceptance" in the relevant scientific community.⁵⁷ Many decades later, the United States Supreme Court overhauled the *Frye* standard in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* by holding that the adoption of Federal Rules of Evidence⁵⁸ superseded it.⁵⁹

Rule 702 governs the admissibility of testimony by experts, and provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.⁶⁰

Explaining that the drafting history of the Rules fails to mention *Frye* and that a "rigid 'general acceptance'" standard would conflict with the "'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony,'" the *Daubert* Court rejected the argument that

⁵⁵ 293 F. 1013 (D.C. Cir. 1923) (holding that the admissibility of scientific expert testimony depends upon its "general acceptance" in the relevant scientific community).

⁵⁶ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 570, 585 (1993) (characterizing *Frye* as the "dominant standard" in the 70 years between that case and *Daubert*).

⁵⁷ 293 F. 1014 (applying this rule to find that the systolic blood pressure measure deception test does not have scientific recognition among psychological authorities).

⁵⁸ All textual references to "Rule(s)" refer to the Federal Rules of Evidence.

⁵⁹ See *Daubert*, 509 U.S. 579-601 (focusing on tests governing admissibility of scientific evidence).

⁶⁰ FED. R. EVID. 702.

the Rules assimilated *Frye*.⁶¹ However, it cautioned that the Rules do place some limits on the admissibility of "purportedly scientific evidence."⁶² Under Rule 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only *relevant*, but *reliable*."⁶³ "Expert testimony [that] does not relate to any issue in the case is not relevant and, ergo, non-helpful."⁶⁴

2. Applying the *Daubert* Factors to Practice Guidelines

In light of the *Daubert* Court's adoption of the Federal Rules of Evidence, a trier of fact essentially has two tasks with respect to the use of practice guidelines in a malpractice action. First, the court must determine whether the guidelines are admissible as evidence of the standard of care. In ruling on the admissibility of guidelines, the court must determine: (1) whether the guidelines are *relevant* to the conduct in question; and (2) whether they are *reliable* sources for delineating sound or proper medical practice.⁶⁵ Whether guidelines are deemed relevant and reliable by courts will ultimately drive the decision of whether to give them conclusive or merely persuasive weight in ascertaining the standard of care. Part of this inquiry is considering whether the standard articulated in the proffered guideline has risen to the level of a nationally accepted standard, and whether a respectable alternative school of thought exists.⁶⁶ Second, if a guideline is offered as an affirmative defense, the trier of fact (i.e., judge or jury) must decide whether the defendant followed it appropriately in making treatment or coverage decisions, prescribing medical products, or rendering medical care.

It follows that the burdens on the parties seeking to introduce guidelines as yardsticks against which a provider's con-

⁶¹ See *Daubert*, 509 U.S. at 588-89 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988) (citing FED. R. EVID. 701-05)).

⁶² See *id.* at 589 (analyzing the Federal Rules of Evidence as they compare to the *Frye* test).

⁶³ *Id.* (emphasis added).

⁶⁴ *Id.* at 591 (quoting 3 J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE ¶ 702[02], at 702-18 (1988)).

⁶⁵ See *id.* at 589 (discussing a judge's standard of review when deciding to admit or exclude scientific evidence).

⁶⁶ See discussions on "Two Schools of Thought: Fall-Back Position," *infra* section III. C.2.b.iv.(B).; *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932), *cert. denied*, 287 U.S. 662 (1932), *infra* section IV.B.

duct are measured will depend on how courts regard guidelines. Currently, the burden remains on the party desiring to admit the guidelines to establish both of these attributes, and the opposing party has the opportunity to refute their applicability. In the future, if certain sets of guidelines, such as those approved by nationally recognized and highly regarded medical associations, are conclusively deemed reliable so that expert testimony is no longer a prerequisite to their admissibility, then the party seeking to introduce them may only need to enlist experts to vouch for their relevance to the conduct in question. In other words, expert testimony will first be employed to establish whether the particular guideline was appropriately used or should have been used to guide the physician in screening, diagnosing, or treating the patient. It will then be utilized to demonstrate whether the defendant faithfully followed the guideline.

a. Relevance Under *Daubert*

Rule 401 defines "relevant evidence" as:

[E]vidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Relevance depends, in part, on a patient's profile in terms of age, race, family history, and other medical conditions. Thus, a particular guideline may be relevant to a patient with the condition addressed in the guideline, but may be inapplicable to another patient with the same condition who is older and has additional medical problems. For example, guidelines for coronary failure may be irrelevant where a patient also suffers from diabetes. Likewise, surgical intervention that would be appropriate for a middle-aged patient may be too risky for an elderly patient with the same medical problem. Therefore, as a preliminary matter, a trial judge must assess whether a guideline can be properly applied to the facts of the particular case.⁶⁷ Either both parties will agree on the relevance of the guideline to estab-

⁶⁷ See *Daubert*, 509 U.S. at 592-93 (discussing the judge's preliminary assessment of the admissibility of scientific evidence).

lishing the standard of care, or the party seeking to introduce it will have the burden to prove affirmatively the relevance.⁶⁸

Three major factors interact in ascertaining whether a guideline is relevant to a particular case. First, the primary objective of the guideline must have been consistent with the physician's screening, diagnosis, or treatment objectives.⁶⁹ Second, the recommendations contained in the guideline must be applicable to the plaintiff.⁷⁰ More specifically, the plaintiff must have been the guideline's intended target.⁷¹ If the plaintiff carries risk factors not contemplated by the guideline drafters, then the guideline might be deemed irrelevant. Good guidelines allow for the variables of an individual patient. Flexibility may be indicated by traits that require individualized recommendations or that rationalize departing from the standards.⁷² For example, the American College of Physicians, the College of Cardiology, and the American Heart Association warn against using electrocardiograms for screening asymptomatic adults, while acknowledging that this advice might not apply to individuals who smoke, are male and beyond a certain age, or have hypertension or diabetes.⁷³ A third indicia of relevance is whether a guideline accounts for significant new developments in medical research and technology. Courts should consider two important dates: (1) the date of publication of the most recent evidence employed; and (2) the date the final recommendations contained in

⁶⁸ See Hirshfeld, *supra* note 14, at 155.

⁶⁹ See Mark C. Wilson et al., *Users' Guides to the Medical Literature: How To Use Clinical Practice Guidelines: What Are the Recommendations and Will They Help You in Caring for Your Patients?*, 274 JAMA 1630, 1631 (1995) (explaining the use of practice guidelines).

⁷⁰ See *id.*

⁷¹ See *id.*

⁷² See *id.*

⁷³ See *id.* (citing Harold C. Sox, Jr. et al., *The Role of Exercise Testing on Screening for Coronary Heart Disease*, 110 ANNALS INTERNAL MED. 456-69 (1989); Harold C. Sox, Jr. et al., *The Resting Electrocardiogram as a Screening Test: A Clinical Analysis*, 111 ANNALS INTERNAL MED. 489 (1989)); American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures, Subcommittee on Exercise Testing, *Guidelines for Exercise Testing*, 8 J. AM. C. CARDIOL. 725, 729-38 (discussing characteristics that may determine the appropriateness of using certain tests for screening); American College of Physicians, *Screening for Asymptomatic Coronary Artery Disease: The Resting Electrocardiogram*, in COMMON SCREENING TESTS, app. at 398 (David M. Eddy ed., 1991); American College of Physicians, *Screening for Asymptomatic Coronary Artery Disease: Exercise Stress Testing*, in COMMON SCREENING TESTS, app. at 400-01 (David M. Eddy ed., 1991).

the guideline were made.⁷⁴ Out-of-date guidelines may be irrelevant per se in light of new medical developments.

b. Reliability Under *Daubert*

A party may establish reliability by asking the court to qualify the guideline under Rule 803(18) – the “learned treatise exception” to the rule against the admissibility of hearsay – by enlisting an expert to testify that leading members of the medical profession consider the guideline to be authoritative. Under this Rule, the following is exempted from the prohibition against bringing hearsay into a case:

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.⁷⁵

The advisory committee’s note to this exception explains that, although the admissibility of learned treatises has generally been favored, “the great weight of authority” opines that they should not be independently admissible as substantive evidence without relying on expert testimony.⁷⁶ In other words, “[t]he Rule avoids the danger of misunderstanding and misapplication by limiting the use of treatises as substantive evidence to situations in which an expert is on the stand and available to explain and assist in the application of the treatise if desired.”⁷⁷ Eventually, if guidelines become consistently accepted, then they might be admitted into evidence by judicial notice,⁷⁸ a tool that enables the judge to recognize reliability and enter exhibits sub-

⁷⁴ See Robert S.A. Hayward et al., *Users’ Guides to the Medical Literature: How To Use Clinical Practice Guidelines: Are the Recommendations Valid?*, 274 JAMA 570, 573 (1995) (noting that guidelines may be outdated due to the time required to assemble evidence and achieve a consensus on recommendations).

⁷⁵ FED. R. EVID. 803(18).

⁷⁶ *Id.*, advisory committee’s note.

⁷⁷ *Id.*

⁷⁸ See FED. R. EVID. 201 (stating the applicability of judicial notice to adjudicative factors).

stantively into evidence without the need for battles of experts to vouch for their potential value.⁷⁹ The possibility of using judicial notice to bring guidelines into the courtroom would require that they become so well known that reliability would be presumed. However, given the lack of consensus among medical associations throughout the nation, judicial notice could only be used in rare cases where the validity of a guideline is absolutely incontrovertible.

Declining to articulate a "definitive checklist or test," the *Daubert* Court proffered four "general observations" as guidance in determining reliability.⁸⁰ First, it suggested that a judge inquire into whether the scientific theory or technique at issue "can be (and has been) tested."⁸¹ A second relevant, but not dispositive, factor is whether it has been through "peer review and publication."⁸² However, "[p]ublication . . . is not a sine qua non of admissibility; it does not necessarily correlate with reliability."⁸³ On the contrary, there are valuable theories that may be too new to be published.⁸⁴ Third, a court "should consider the known or potential rate of error,"⁸⁵ and the "existence and maintenance of standards controlling the technique's operation."⁸⁶ Finally, "general acceptance" can be a factor in a court's inquiry into reliability.⁸⁷ Whereas prevailing acceptance can be an important factor, a known technique with only minimal support in the scientific community is appropriately "viewed with skepticism."⁸⁸ The Court then summarized its suggestions:

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission.

⁷⁹ See FED. R. EVID. 803(18).

⁸⁰ See *Daubert*, 509 U.S. at 593 (discussing the judge's preliminary assessment of the admissibility of scientific evidence).

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.* (citing S. JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS* 61-76 (1990)).

⁸⁴ See *id.*

⁸⁵ See *Daubert*, 509 U.S. at 594 (citing *United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989)).

⁸⁶ *Id.* (citing *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978)).

⁸⁷ *Id.*

⁸⁸ *Id.*

The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.⁸⁹

Although only proffered in dicta, the *Daubert* framework for determining reliability provides a useful tool in weighing whether a particular guideline should be admitted as evidence of the standard of care, and also provides a guide for the future of the judicial use of practice guidelines. These factors may ultimately determine which guidelines should be afforded conclusive weight as substantive evidence.

i. Testable Theories Under *Daubert*

The first step in establishing reliability of practice guidelines is demonstrating that the scientific theory or technique at issue "can be (and has been) tested."⁹⁰ Fortunately, modern medicine allows the medical profession to ascertain, through outcomes and effectiveness research, precisely which approaches tend to yield better results.⁹¹ Use of today's sophisticated computer technology and the development of more thorough treatment data on a national scale could make this goal ascertainable.⁹²

The *Daubert* Court explained that "scientific knowledge" must be based on the scientific method, and announced the requirement that expert testimony relate to scientific knowledge in order to establish a standard of reliability.⁹³ The scientific, evidence-based approach is currently the most widely accepted method for guideline creation.⁹⁴ This approach includes structured and comprehensive reviews of scientific literature, synthesis and evaluation of the literature, and expert panel review.⁹⁵

⁸⁹ *Id.* at 594-95.

⁹⁰ *See Daubert*, 509 U.S. at 593.

⁹¹ *See* Rosoff, *supra* note 8, at 371-72 (discussing the potential benefits of clinical practice guidelines).

⁹² Dr. David Eddy is a leader in this pursuit. *See id.* at 372 (citing David M. Eddy, *Clinical Decision Making: From Theory to Practice* (pts. 1-4) 263 JAMA 287, 441, 1265 (1990)).

⁹³ *See Daubert*, 509 U.S. at 589-90 (discussing standards of admissibility for expert testimony).

⁹⁴ *See* Travis & Bell, *supra* note 34, at 126 (concluding that the scientific evidence approach is the more widely accepted method for managed care guideline development versus consensus-based guideline development).

⁹⁵ *See id.*

Thus, another indication of reliability is whether, given the same evidence and methods for guidelines development, a different set of experts yield virtually the same statements.⁹⁶

In the mid-1980s, the Institute for Health Care Quality, a guidelines development company located in Minneapolis, Minnesota, initiated a model for evidence-based guidelines, which has been adopted by the AMA and AHCPR.⁹⁷ In addition, Health Risk Management, Inc. developed a set of electronic interactive guidelines, called the "QualityFIRST Medical Risk Management System," in an effort to improve overall quality of care and decrease inconsistencies.⁹⁸ These guidelines epitomize the standard for reliability in that they are evidence-based, reviewed by internationally acclaimed panels of experts, and updated annually to reflect changes in what is considered "best-practice."⁹⁹

ii. Peer Review and Publication Under *Daubert*

The second reliability factor is whether the guideline has undergone "peer review and publication."¹⁰⁰ A judge weighing this attribute, however, should acknowledge that "[p]ublication is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability."¹⁰¹ Peer reviewers may approve or reject certain guidelines based on their own biases rather than on the objective validity of the guidelines.¹⁰² Moreover, certain types of legitimate guidelines, by definition, may escape external peer review. For example, actuarially derived guidelines may reflect scientifically tested principles, but are not subjected to the peer review process. In addition, guidelines developed by professional organizations, such as the AMA, may only be approved internally.

⁹⁶ See IOM I, *supra* note 2, at 30.

⁹⁷ See Travis, *supra* note 34, at 126 (citing IOM II, *supra* note 5, and AMERICAN MEDICAL ASSOCIATION, ATTRIBUTES TO GUIDE THE DEVELOPMENT AND EVALUATION OF PRACTICE PARAMETERS/GUIDELINES (1996)).

⁹⁸ See *id.* at 127 (discussing specifics of a development by Health Rise Management, Inc. to improve quality in health care decision-making).

⁹⁹ See *id.* at 130 (explaining how guidelines can be applied to improve reliability and outcomes in managed care organizations).

¹⁰⁰ See *Daubert*, 509 U.S. at 593 (discussing guidelines for determining the admissibility of scientific evidence).

¹⁰¹ *Id.* (citing SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS 61-76 (1990)).

¹⁰² See Hayward, *supra* note 74, at 574.

iii. Rate of Error Under *Daubert*

Third in the reliability inquiry, a court "should consider the known potential rate of error"¹⁰³ and the "existence and maintenance of standards controlling the technique's operation."¹⁰⁴ As a corollary, the credibility of guidelines will depend on the drafters' candor about the uncertainties regarding the harms or benefits of the suggested interventions, and whether the recommendations provide flexibility in accommodating those uncertainties inherent to even thoroughly conducted clinical trials.¹⁰⁵ Medical opinions provide meaningful guidance where scientific objectivity leaves gaps. Reliable guidelines acknowledge the use of opinions, as well as the existence of differing views, to allow room for "legitimate disagreement."¹⁰⁶ In such instances, guidelines may be deemed reliable as a lower threshold for what a trier of fact should consider proper action by a health care provider, but may not be afforded conclusive weight. Therefore, further evidence or expert testimony will be necessary to determine whether the practitioner exercised the judgement of a reasonably prudent practitioner under similar circumstances to determine the ultimate question of liability.

An attribute of unreliability is presentation of misleading quantitative standards. Guideline drafters attempting to mask the existence of uncertainty may enumerate numerical thresholds to provide *post-hoc*, but artificial, certainty. For example, a guideline may suggest that "twelve hours" of a particular symptom is indicative of a medical problem, rather than admit that "[t]he optimal duration of hemodynamic monitoring is uncertain."¹⁰⁷ To rectify the problems that ensue when medical providers rely blindly on arbitrary numbers that falsely purport to be scientifically sound, national or governmental organizations should create a consistent and quantifiable scale for weighing the strength and efficacy of scientific data.

¹⁰³ See *Daubert*, 509 U.S. at 594 (citing *U.S. v. Smith*, 869 F.2d 348, 353-54 (7th Cir.1989)).

¹⁰⁴ *Id.* (citing *U.S. v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978)).

¹⁰⁵ See Stephen H. Woolf, *Do Clinical Practice Guidelines Define Good Medical Care?: The Need for Good Science and the Disclosure of Uncertainty When Defining "Best Practices,"* 113 CHEST 166S, 168S (1998) (describing how practice guidelines promote the best care through confidence, but admonishing that these guidelines should acknowledge the uncertainty of the scientific evidence relied upon).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* (internal citation omitted).

Furthermore, reliability can be judged according to whether the drafters have done an adequate job of collecting and synthesizing scientific evidence.¹⁰⁸ To ascertain this, courts can consider whether the guidelines define the evidence used, report how it was chosen and incorporated, refer explicitly to the crucial data so that a guideline user can review it, and report randomized clinical trials that reveal a causal relationship between the recommended interventions and healthy outcomes.¹⁰⁹ Ideally, good guidelines are based on a systematic approach to appraising and classifying the evidence upon which the guideline developers principally rely.¹¹⁰

iv. General Acceptance Under *Daubert*

Another indication of reliability is whether, given the same clinical circumstances, practitioners interpret and apply the same guidelines consistently.¹¹¹ In other words, "general acceptance" is an important factor in establishing reliability,¹¹² although not dispositive, as it was under *Frye*. In a time where the practice of medicine is becoming increasingly globalized, one way to define general acceptance is through national acceptance. The accurate diagnosis of a medical condition and the selection of appropriate treatment responses should not vary according to geographic region.¹¹³ Instead, medical decisions "should be based on universally accepted, evidence-based standards."¹¹⁴ Ideally, practice guidelines would invariably reflect custom. In reality, however, the delivery of health care depends on the amount of local resources,¹¹⁵ and what is customary practice constantly evolves in a world where medical technology advances exponentially.

¹⁰⁸ See Hayward et al., *supra* note 74, at 572 (citing A.D. Oxman et al., *Users' Guide to the Medical Literature: I. How to Use an Overview*, 272 JAMA 1367 (1994)) (arguing that developers must identify and consider all relevant evidence when formulating guidelines).

¹⁰⁹ See *id.*

¹¹⁰ See *id.*

¹¹¹ See IOM I, *supra* note 2, at 30.

¹¹² See *Daubert*, 509 U.S. at 594 (discussing standards of the admissibility of scientific evidence).

¹¹³ See *id.*

¹¹⁴ Travis & Bell, *supra* note 34, at 123 (arguing that accurate diagnosis and optional treatment should be based on "universally accepted, evidence-based standards," resulting in similar and efficient health care systems regardless of different geographic regions).

¹¹⁵ See *id.*

In addition, it is widely acknowledged that clinical practice varies substantially between geographic regions. A vast body of evidence, typified by the work of John Wennberg at the Dartmouth Medical School and Robert Brook at the University of California, reveals these inconsistencies.¹¹⁶ Variations are found in which procedures are used to treat a given condition and in lengths of hospital stays.¹¹⁷ Discrepancies exist even between geographically proximate communities.¹¹⁸ In 1973, Dr. Wennberg discovered that the chance of having a tonsillectomy by age fifteen was twelve percent in Waterbury, Vermont, but as high as sixty percent in nearby Stowe, Vermont.¹¹⁹ According to subsequent studies, these differences were not attributable to demographics, such as age, socioeconomic status, access to care, or morbidity.¹²⁰ Rather, they were explained by the independent judgment of treating physicians on the appropriateness of the surgical procedure.¹²¹ These studies reveal the difficulty of achieving "general acceptance," insofar as this remains a factor after the overhaul of the *Frye* test for admissibility. They also indicate that reducing the inappropriate use of certain procedures depends on the creation of scientifically sound, evidence-based guidelines for clinical decision-making.¹²²

(A) Efforts Aimed at National Acceptance of Guidelines

More specifically, national acceptance is an important indication of reliability. For example, the AMA launched the Clinical Practice Guideline Recognition Program, a national pilot project designed to allow physicians to identify which practice guidelines have been developed in accordance with scientific

¹¹⁶ See Rosoff, *supra* note 8, at 371 (citing John E. Wennberg, *Dealing With Medical Practice Variations: A Proposal for Action*, HEALTH AFF., Summer 1984, at 6, and John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. MED. 811, 812-17 (1982)) (proposing that clinical procedures and rules vary among different geographic regions by comparing surgical practices and procedures in hospital service areas within particular states).

¹¹⁷ See *id.*

¹¹⁸ See Travis & Bell, *supra* note 34, at 121 (citing JOHN E. WENNBURG & ALAN M. GITTELSON, SMALL AREA VARIATIONS IN HEALTH CARE DELIVERY (reprint Dec. 14, 1973)).

¹¹⁹ See *id.*

¹²⁰ See *id.*

¹²¹ See *id.*

¹²² See *id.* at 122.

cally based criteria.¹²³ According to one member of the AMA's Board of Trustees, Yank D. Coble, not only must guidelines be scientifically sound, but "physicians must have confidence in their integrity."¹²⁴

Knowing that a certain guideline's development has met the AMA's strict standards will give physicians, and their patients, the assurance they need . . . the Clinical Practice Guideline Recognition Program is the AMA's response to growing concerns among physicians about misapplication of clinical practice guidelines by some insurers, the proliferation of proprietary guidelines of questionable scientific integrity, and the funding of guidelines by pharmaceutical firms that may preferentially suggest the use of their products.¹²⁵

The AMA bases its evaluations of the guidelines on criteria gleaned from "Attributes to Guide the Development and Evaluation of Practice Parameters/Guidelines," created by the Practice Parameters Partnership and the Practice Parameters Forum, groups that include the AMA, the AHCPR, the American Hospital Association (AHA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), national medical specialty societies, and state, county, and metropolitan physician organizations.¹²⁶ Those guidelines that satisfy specified criteria will be deemed "AMA Recognized Clinical Practice Guidelines," and the AMA will publish all approved guidelines in the "Directory of Clinical Practice Guidelines."¹²⁷

(B) "Two Schools of Thought" Fall-Back Position

Even if guidelines satisfy national standards, the judicial system cannot ignore the reality that some degree of regional variation is inevitable. Therefore, it should continue to consider the "two schools of thought" theory that allows for regional, but legitimate, variation in standards of care where the alternatives are also deemed medically legitimate by well-respected mem-

¹²³ See American Medical Ass'n, AMA Launches Clinical Practice Guideline Recognition Program to Evaluate Guidelines, Press Release, July 16, 1997.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ See *id.*

¹²⁷ See *id.*

bers of the medical profession. This doctrine allows physicians to defend their treatment choices in situations where hospitals or small physician practices have limited resources and cannot necessarily utilize the most expensive equipment or technology.

For example, a diagnostic guideline that may be applied feasibly in Manhattan where multiple MRI scanners may be located only blocks apart will not be practical in rural Montana.¹²⁸ Similarly, whereas the American College of Obstetrics and Gynecology recommends mammograms every one to two years for women aged forty to forty-nine, the American Cancer Society urges annual mammography.¹²⁹ Furthermore, multiple guidelines for the same treatment, diagnosis, or procedure may continue to circulate throughout a specialty community. Even where national standards come to dominate the practice of medicine, it is only logical for the judicial process to continue to allow courts to recognize that deviation from such standards does not constitute malpractice per se.

v. Other Indicia of Reliability Under *Daubert*

Promulgation of reliable guidelines requires more outcomes research. For example, it is important to understand the difference between what factors lower cholesterol levels and what effect reducing cholesterol has on healthy outcomes, and how a cost-effectiveness analysis applies to this clinical scenario.¹³⁰ More funding is needed for that kind of research.¹³¹ Typically, malpractice suits arise out of claims that a patient suffered a bad outcome that resulted from a flawed process.¹³² First, a physician might have failed to carry out an intervention indicated by a guideline.¹³³ Second, a physician might have carried out an intervention that was not indicated.¹³⁴ Third, a physician might have improperly followed a guideline, e.g., botched a procedure.¹³⁵ However, guidelines in their current form are of no use in the last example unless they articulate the predicted outcomes

¹²⁸ See Crane, *supra* note 22, at 240 (observing that clinical guidelines will sometimes vary substantially by location due to the density of medical resources).

¹²⁹ See *id.*

¹³⁰ Telephone Interview with Brad Moore, M.D., M.P.H. (Mar. 17, 1999).

¹³¹ See *id.*

¹³² See Peter G. Goldschmidt, *Can Practice Guidelines Reduce Malpractice Claims?*, 267 JAMA 2602 (1992) (discussing the utility of practice guidelines).

¹³³ See *id.*

¹³⁴ See *id.*

¹³⁵ See *id.* at 2602-03.

of following them.¹³⁶ Furthermore, good guidelines will improve the quality of care rendered, thereby preventing bad outcomes, rather than just helping the few plaintiffs who bring malpractice suits.¹³⁷

Availability of outcomes data is another indication of reliability. Outcomes information can be found in a guideline's policy statement or supporting article. First, by including information about how the options and outcomes contained were chosen, or by explaining certain data or value choices, hence demonstrating that the guidelines were created in a systematic fashion, guidelines can provide physicians or courts with the tools necessary to make informed evaluations on their utility.¹³⁸ More specifically, whether they are intended for screening, diagnosis, or treatment purposes, guidelines should specify both the recommended interventions and sensible alternatives.¹³⁹

Guidelines that omit alternatives are likely to lack reliability. For example, an American College of Physicians (ACP) guideline based on a careful review of the literature provides interventions for preventing strokes.¹⁴⁰ Although the guideline's preamble suggests carotid endarterectomy as a possible surgical intervention, the guideline itself fails to mention this highly effective procedure in the disease management context.¹⁴¹ Moreover, a good guideline should not only include management options, but also the consequences of these options, defined by morbidity, mortality, quality of life for the patient, patient preferences, as well as economic outcomes for the patient and the health care system as a whole.¹⁴²

¹³⁶ See *id.* at 2603.

¹³⁷ See *id.*

¹³⁸ See Robert S.A. Hayward et al., *supra* note 74, at 571 (Aug. 16, 1995) (citing Hayward et al., *More Informative Abstracts of Articles Describing Clinical Practice Guidelines*, 188 ANNALS INTERNAL MED. 731 (1993)) (exploring the need to rely upon only those guidelines that have been tested through systematic methodology).

¹³⁹ See *id.*

¹⁴⁰ See *id.* (citing D.B. Matchar et al., *Medical Treatment for Stroke Prevention*, 121 ANNALS INTERNAL MED. 54 (1994)).

¹⁴¹ See *id.* (citing North American Symptomatic Carotid Endarterectomy Trial Collaborators, *Beneficial Effect of Carotid Endarterectomy in Symptomatic Patients with High-Grade Carotid Stenosis*, 325 NEW ENG. J. MED., at 758 (1991)).

¹⁴² See *id.* at 572.

IV. THE DEGREE OF CONCLUSIVE WEIGHT AFFORDED TO GUIDELINES REQUIRES OPPORTUNITIES TO CHALLENGE THE STANDARD OF CARE

A. Establishing Standards of Care

Before guidelines can significantly improve the evidentiary process in terms of efficiency and consistency, the standards of care themselves must be satisfactorily established. Today, too many court battles are waged on the fundamental issue of what constitutes customary practice for purposes of establishing the benchmark standard of care with which a reasonable physician is expected to comply.

Unless it is determined conclusively that the guidelines developed in an initiative such as the Maine Medical Liability Demonstration Project, discussed in Section VI.B., are reliable, it is unfair to deprive parties of the opportunity to challenge the guidelines themselves. This only places a "band-aid" on the problem of lengthy courtroom battles over what guidelines should be deemed conclusive as the standard of care, without going through the indispensable process of ascertaining what guidelines truly are the most appropriate for a particular condition.

B. Challenging the Standard of Customary Practice

*The T.J. Hooper*¹⁴³ sparked the judiciary's recognition that parties can challenge what is considered customary practice in an industry. This opinion has provided the basis for the notion that even a diagnosis or treatment approach established as standard practice cannot constitute conclusive evidence to establish a breach of duty. Two barges were lost in a gale because their tugs were not equipped with radios that would have transmitted a weather report of a dangerous storm.¹⁴⁴ In a widely cited opinion, the Second Circuit determined that, although the tugs

¹⁴³ 60 F.2d 737 (2d Cir. 1932), *cert. denied*, 287 U.S. 662 (1932) (discussing liability of a tugboat operator for not conforming to industry practices).

¹⁴⁴ *See id.* at 738-39.

comported with custom, the custom itself was vulnerable to attack:

Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It may never set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission But here there was no custom at all as to receiving sets; some had them, some did not; the most that can be urged is that they had not yet become general. Certainly in such a case we need not pause; when some have thought a device necessary, at least we may say that they were right, and the others too slack.¹⁴⁵

A more recent case reiterates *The T.J. Hooper's* mantra. In *United Blood Services v. Quintana*,¹⁴⁶ Mrs. Quintana received HIV-infected blood from a transfusion. The defendant blood bank had comported with the precautionary standards contained in guidelines that were current at the time and were issued by, *inter alia*, the American Red Cross and the FDA.¹⁴⁷ Although the trial court admitted into evidence the standards and testimony regarding the blood bank's compliance with the guidelines, it rendered a pretrial ruling that the plaintiffs could not present expert medical testimony on the allegedly substandard nature of the screening and testing procedures employed by the blood banking industry at the time of Mrs. Quintana's transfusion and of their unreasonably deficient ability to prevent the transmission of AIDS through transfusion.¹⁴⁸

In relevant part, the Supreme Court of Colorado granted certiorari to consider whether the court of appeals erred in determining that the trial court erred in precluding presentation of evidence that "might tend to show that the customs and practices in the defendant's industry might not be reasonable and

¹⁴⁵ *Id.* at 740 (internal citations omitted).

¹⁴⁶ 827 P.2d. 509 (Colo. 1992) (discussing the standard of care applied to blood banks).

¹⁴⁷ *See id.* at 514-17 (explaining how United Blood Services revised its donor-screening process in response to recommendations from the Red Cross and the FDA).

¹⁴⁸ *See id.* at 516-17.

prudent, and by instructing the jury that defendant's compliance with these regulations, customs, and practice established, as a matter of law, the absence of negligence."¹⁴⁹ In other words, the blood bank's compliance with guidelines constituted some evidence of due care, but did not serve as conclusive proof that additional precautions were unnecessary. In affirming the court of appeals' decision, the Supreme Court of Colorado relied on *The T.J. Hooper* in opining that satisfying the professional standard of care is not necessarily conclusive proof of due care in a negligence case.¹⁵⁰ It further explained:

If the standard adopted by a practicing profession were to be deemed conclusive proof of due care, the profession itself would be permitted to set the measure of its own legal liability, even though that measure might be far below a level of care readily attainable through the adoption of practices and procedures substantially more effective in protecting others against harm than the self-decreed standard of the profession.¹⁵¹

The court opined that the presumption that following the professional standard of care constitutes due care is rebuttable by the party challenging the standard itself.¹⁵² The jury must decide whether a preponderance of the evidence indicates that the standard is "unreasonably deficient," relying on all evidence pertaining to the profession's practices and procedures.¹⁵³ The *Quintana* court ultimately held that the blood bank's conduct was to be judged by a professional standard of care ascertained through expert testimony.¹⁵⁴

¹⁴⁹ *Id.* at 518 (citing the lower court opinion in *Quintana v. United Blood Services*, 811 P.2d 424, 431-32 (Colo. App. 1991)).

¹⁵⁰ *See id.* at 520 (noting that satisfying the standard of care set by a profession does not exclusively prove that the professional has exercised due care).

¹⁵¹ *Id.*

¹⁵² *See id.* at 521.

¹⁵³ *See id.*

¹⁵⁴ *See id.* at 523-24.

V. HOW COURTS HAVE APPROACHED THE ADMISSIBILITY OF GUIDELINES

A. Admissibility Through Expert Testimony

Currently, courts that decide to admit guidelines into evidence usually will only allow them to be presented through expert testimony, but not as independent exhibits. However, some appellate courts have upheld trial court decisions to admit them independently, thereby allowing jurors to rely on the guidelines substantively where they merely reflect ideas about which an expert would have testified. In *Frakes v. Cardiology Consultants, P.C.*,¹⁵⁵ a malpractice case concerning a man who died of cardiac arrest, the Tennessee Court of Appeals found that the trial court did not commit error in admitting exercise test parameters in the form of a printed table and allowing the table to be present in the jury room during deliberations even though it was not formally admitted into evidence until after the jury retired.¹⁵⁶ The jury had the task of deciding whether the defendant doctor deviated from the recognized standard of acceptable professional practice, as articulated in a consensus statement on exercise tread mill tests included in a brochure produced by the American College of Cardiology and the American Heart Association.¹⁵⁷

The appellate court deferred to the lower court's judgment that the parameters were relevant in ascertaining the standard of care and that they would assist the jury in understanding a difficult topic.¹⁵⁸ The trial judge had opined that use of the table had the same effect as if the expert witness stood at a display board in the courtroom and listed the applicable standards.¹⁵⁹ "By the end of the trial the exhibit was simply a statement of what at

¹⁵⁵ No. 01-A-01-9702-CV—00069, 1997 WL 536949 (Tenn. App. Aug. 29, 1997).

¹⁵⁶ See *id.* at *5 (indicating that "the table was admitted because the court believed it had been thoroughly explained, that all expert witnesses had conceded that it was relevant in determining the standard of care, and that it would aid the jury in understanding a difficult subject").

¹⁵⁷ See *id.* at *2 (adding that the guidelines were entitled "Exercise Test Parameters Associated With Poor Prognosis and/or Increased Severity of [Coronary Artery Disease]").

¹⁵⁸ See *id.* at *5 (providing that, although the timing of the table's admission was unfortunate, it was not prejudicial).

¹⁵⁹ See *id.* at *4 (expressing that this was not a circumstance where a jury was exposed to unexamined hearsay).

least two experts testified was the standard of care with respect to reading the test results.”¹⁶⁰ Rather than allow it in as market report or commercial publication excepted from the Tennessee rule against hearsay, the court relied on the fact that two of the three experts testified that it reflected the professional standard of care.¹⁶¹ Furthermore, all experts questioned conceded that the table was relevant in identifying the standard of care and assisted the jury in its decision-making process.¹⁶² The key to this ruling was the determination that the table lacked any independent value in the absence of expert testimony certifying its relevance. Thus, the trial court did not commit harmful error in admitting it.¹⁶³

A concurring judge in *Frakes* praised practice guidelines as “systematically developed statements” developed to help physicians and patients make appropriate medical decisions.¹⁶⁴ He further explained that they can be more than “a mere sampling of professional opinion” by providing “consensus standards of conduct that are both clearer and more rational than those currently used to identify professional negligence.”¹⁶⁵ Although urging that guidelines “can be extremely helpful” in cases where a physician allegedly chose the wrong course of action or neglected to take further action, the concurrence cautioned that “they should not necessarily be viewed as conclusive evidence of the standard of care.”¹⁶⁶

B. How the Use of Guidelines in Insurance Documents Informs the Malpractice Debate

Courts have examined the use of practice guidelines in the insurance context as well. Insurance companies use them to substantiate benefit denials based on lack of medical necessity. The defendants in *Weaver v. Reagan*¹⁶⁷ were directors of the Missouri Department of Social Services and Division of Medical Services who relied on FDA protocol to defend their deci-

¹⁶⁰ *Id.*

¹⁶¹ *See id.* at *5 (adding that a third expert implied that the table was not wholly accurate or complete but did embody the consensus standard among cardiologists).

¹⁶² *See id.*

¹⁶³ *Id.*

¹⁶⁴ *See id.* at *6 (J. Koch, concurring) (calling for the Court to address the procedure and administration aspects of using such guidelines).

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ 886 F.2d 194 (8th Cir. 1989).

sion to limit coverage of AZT to Medicaid patients who met certain criteria.¹⁶⁸ The court ruled that using the protocol in medical necessity and utilization control decisions was neither intended to interfere with the practice of medicine nor to keep doctors from exercising their best professional judgment.¹⁶⁹

This type of coverage case is distinguishable from the medical malpractice line of cases presented in this Article. In *Weaver*, the defendants used guidelines to make treatment decisions,¹⁷⁰ whereas plaintiffs and defendants in malpractice cases tend to use guidelines as post hoc rationalization for or against medical decisions. Courts seem to be less likely to disturb a coverage decision based on legitimate guidelines than to afford conclusive weight to guidelines in determining malpractice.

Similar to *Weaver*, in *Harris v. Mutual of Omaha Cos.*,¹⁷¹ the Seventh Circuit recognized the necessity of performing high-dose chemotherapy with autologous bone marrow transplants (HDC-ABMT) pursuant to a guideline that set forth the treatment regimen in detail.¹⁷² The guideline enumerated three objectives: (1) to establish response rate and duration in breast cancer treated with HDC-ABMT; (2) to determine toxicity associated with the treatment regimen in patients with high-risk primary and advanced breast cancer; and (3) to determine the length of survival of patients treated with the regimen.¹⁷³ The insurance plan brochure listed three types of reliable evidence for purposes of establishing the experimental or investigational nature of a particular treatment: (1) published reports and articles in the medical and scientific literature deemed authoritative; (2) written protocols employed by the treating facility or those of another facility studying the same drug, device, treatment, or procedure; and (3) written informed consent utilized by the treating facility or another facility studying the same drug,

¹⁶⁸ See *id.* at 198.

¹⁶⁹ See *id.*

¹⁷⁰ *Id.*

¹⁷¹ 992 F.2d 706 (7th Cir. 1993).

¹⁷² See *id.* at 709. The guideline was entitled "Phase II Trial of Standard Induction Therapy Followed by High-Dose Carboplatin/Cyclophosphamide with Standard Dose Etoposide and Autologous Bone Marrow Rescue for Advanced Breast Cancer." The protocol was implemented by an oncologist at Indiana University Medical Center and his colleagues in 1990, but the University Monitoring Committee had not yet confirmed its effectiveness. *Id.*

¹⁷³ See *id.*

device, treatment, or procedure.¹⁷⁴ In affirming the defendant insurer's denial of coverage for HDC-ABMT for an enrollee with breast cancer, the appellate court affirmed the district courts' finding that none of the evidence the plaintiff proffered to counter the guidelines used by the defense was reliable.¹⁷⁵ Thus, the defendant's denial was not arbitrary and capricious and the plain language of the insurance contract forced the court to uphold it.¹⁷⁶

The Tenth Circuit recently went a step further than the Seventh Circuit by refusing to even review the guidelines contained in plan documents in a case brought under the Employee Retirement Income Security Act of 1974 (ERISA). In *Jones v. Kodak Medical Assistance Plan*,¹⁷⁷ the Tenth Circuit reviewed the plan's refusal to pre-certify inpatient alcohol treatment on the grounds that it was not medically necessary and the program was located out-of-state.¹⁷⁸ The district court granted the defendant plan's motion for summary judgment, finding that: (1) the plan administrator's decision was neither arbitrary nor capricious; and (2) the plan did not violate ERISA disclosure requirements by failing to include unpublished criteria prepared by an administrative services company that administered the managed care review process under which the appropriateness of substance abuse treatment was evaluated.¹⁷⁹ The Tenth Circuit affirmed the trial court's finding that the unpublished guidelines were part of the plan's terms and, therefore, that they were not subject to judicial review.¹⁸⁰ It explained that, absent a showing that the criteria were applied in a discriminatory fashion, ERISA's disclosure provisions do not require that a plan summary contain "particularized criteria" for assessing medical necessity in individual circumstances because to do so would

¹⁷⁴ See *id.* at 708.

¹⁷⁵ See *id.* at 713.

¹⁷⁶ See *id.*

¹⁷⁷ 169 F.3d 1287 (10th Cir. 1999) (stating that the beneficiary brought an ERISA action against a plan administrator, seeking benefits for inpatient alcohol treatment).

¹⁷⁸ See *id.* at 1290 (adding that the plan determines the appropriateness of inpatient treatment on the basis of its criteria).

¹⁷⁹ See *id.*

¹⁸⁰ See *id.* at 1291-92 (explaining that the criteria are unreviewable because it was a matter of plan construction rather than implementation).

frustrate the plan summary's purpose – "to offer a layperson concise information that she can read and digest."¹⁸¹

Arguably, this decision suggests a trend away from establishing a stringent set of judicial standards for affording guidelines conclusive weight by raising the bar for a plaintiff to mount a successful attack on a defendant's use of guidelines. However, its implications on the defensive use of guidelines in malpractice litigation remains unclear.

C. Rejecting a "Gold Standard"

As discussed, the success of guidelines as conclusive evidence requires the development of a set of widely acclaimed guidelines. However, the most authoritative guidelines presently in existence – those issued by the Center for Disease Control (CDC) – have not yet fully proven themselves. In *Bragdon v. Abbott*,¹⁸² the U.S. Supreme Court affirmed the First Circuit's holding that a plaintiff who is HIV-positive has a disability within the meaning of the Americans With Disabilities Act (ADA), and that the defendant dentist in the case violated the ADA by refusing to fill the plaintiff's cavities in his dental office out of his belief that rendering routine dental care posed a direct threat to his health and safety.¹⁸³ The First Circuit had found that Ms. Abbott had "adduced competent evidence of reasonable medical judgments by public health officials" by presenting CDC guidelines that specify infection control procedures to be used by dental providers treating HIV-positive patients.¹⁸⁴ It ruled that the guidelines implied that use of these "universal precautions" allows dentists to render routine care

¹⁸¹ *Id.* at 1292 (citing *Stahl v. Tony's Bldg. Materials, Inc.*, 875 F.2d 1404, 1407 (9th Cir. 1989); *Pompano v. Michael Schiavone & Sons, Inc.*, 680 F.2d 911, 914 (2d Cir. 1982)).

¹⁸² 584 U.S. 624 (1998) (holding, *inter alia*, that HIV is an impairment that substantially limits the major life activity of reproduction). The Supreme Court remanded the case back to the First Circuit, and has denied certiorari on a subsequent appeal. *See Abbot v. Bragdon*, 163 F.3d 87 (1st Cir. 1998), *cert. denied* 119 S.Ct. 1805 (1999).

¹⁸³ *See id.*

¹⁸⁴ *See Abbott v. Bragdon*, 107 F.3d 934, 945-46 (1st Cir. 1997), *aff'd* 118 S. Ct. 2196 (1998) (rejecting Dr. Bragdon's reliance on FDA recommendations that those who come into contact with a patient's blood refrain from donating blood for one year).

safely in the private office environment.¹⁸⁵ The court also deemed persuasive Ms. Abbott's reliance on the 1991 American Dental Association Policy on HIV.¹⁸⁶ Although neither set of guidelines state explicitly that further risk-reduction measures are necessary or that treating HIV-positive patients is an inherently safe practice, the court found these conclusions to be implicit in the "detailed delineation of procedures for office treatment."¹⁸⁷

The U.S. Supreme Court, however, found that the First Circuit mistakenly relied on both sets of guidelines because "[t]his evidence is not definitive."¹⁸⁸ The Court rejected the conclusion that they "necessarily contain implicit assumptions conclusive of the point to be decided. The Guidelines set out in the CDC's recommendation that the universal precautions are the best way to combat the risk of HIV transmission. They do not assess the level of risk."¹⁸⁹ Although the guidelines were relevant, the Court did not deem them sufficiently reliable. Thus, it rejected both the CDC guidelines and the American Dental Association policy as having conclusive weight.¹⁹⁰ On remand, the First Circuit reexamined its use of the CDC guidelines and the policy and, again, decided that it properly relied in them as "competent evidence that public health authorities" deem the routine dental treatment to be safe "if undertaken using universal precautions."¹⁹¹

Although the Supreme Court's rejection of a professional association's policy is notable, its disapproval of CDC guidelines is quite surprising. CDC guidelines have historically been

¹⁸⁵ See *id.* at 946 (affirming the district court's holding on appeal from a grant of summary judgment, reasoning that routine dental care to HIV-infected patients did not pose a direct threat to dentists' health, within the exceptions to the Americans with Disabilities Act).

¹⁸⁶ See *id.*

¹⁸⁷ *Id.* at 947.

¹⁸⁸ *Bragdon*, 524 U.S. at 651 (finding that the CDC and the American Dental Association's policies do not provide dispositive assessments of HIV transmission rates).

¹⁸⁹ *Id.* at 651-52 (adding that the Supreme Court cannot be certain whether the ADA guidelines on HIV carry the weight of the First Amendment).

¹⁹⁰ See *id.* at 652 (adding that, without more information, the Court is unable to determine the policy's rate for assessing risks).

¹⁹¹ *Abbott v. Bragdon*, 163 F.3d 87, 89 (1st Cir. 1998) (holding that the "universal precautions" prescribed by the Center for Disease Control were adequate to allow a dentist's performance of a cavity-filling on a patient with asymptomatic HIV without imposing a "direct threat" to himself and others).

hailed as the “gold standard.” Therefore, the Supreme Court’s rejection of them places the future of the evidentiary value of *all* guidelines in question. Although the First Circuit’s refusal to abrogate its conviction that the CDC guidelines were dispositive in this case allows room for the growth of guidelines as powerful evidentiary tools, the Supreme Court prevented the floodgates from opening through its reluctance to allow even nationally acclaimed guidelines to have conclusive weight.

VI. ATTEMPTS AT ELEVATING GUIDELINES TO THE LEVEL OF CONCLUSIVE EVIDENCE

A. The Doctrine of Negligence Per Se

The implementation and enforcement of statutes and regulations also carry implications for the use of practice guidelines in malpractice litigation. For example, the legal doctrine of “negligence per se” provides that a defendant who violates a statute or regulation can be held conclusively negligent, as long as the legislature or agency intended the statute or regulation to address the kind of injury the plaintiff suffered.¹⁹²

It is questionable whether failure to adhere to a protocol promulgated by a private medical association would ever constitute negligence per se, but it is less questionable whether it would apply where guidelines are used as quality assurance or cost containment mechanisms in public programs, such as Medicare.¹⁹³ Because this legal theory depends entirely on the broad presumption that abrogating any duty imposed by a statute or regulation would constitute unreasonable behavior in every case, this application would arguably be too expansive in the practice guidelines context given the diversity of patients for which a given guideline would apply.¹⁹⁴

It is probably impossible to draft parameters that could intellectually direct the management strategy for every possible clinical situation. A statutory directive that parameters always be followed would not be wise public policy – it could cause harm by forcing physicians to follow practice parameters when

¹⁹² See Hirshfeld, *supra* note 14, at 606 (opining that the doctrine would probably not apply in the private context, but could apply in the public context).

¹⁹³ See *id.*

¹⁹⁴ See *id.*

it might be better for the patient to follow an alternative course.¹⁹⁵

For the same reasons, it would also be unreasonable for a legislature to mandate that courts adopt practice guidelines as conclusive of the standard of care.¹⁹⁶ However, as the defending plan did in *Jones v. Kodak*,¹⁹⁷ discussed *supra* section V.B., insurers can contract with their enrollees to base coverage decisions on a specified set of guidelines. A plan would either have to provide specific guidelines in plan documents or incorporate them by reference. Further, as discussed *infra*, conflict of interest questions arise when insurers themselves play a role in the issuance of guidelines that may be based more on cost-saving considerations than on scientifically sound reasoning.

Statutes could also potentially insulate from liability practitioners who adhere to guidelines.¹⁹⁸ The language contained in one particular federal statute may come to have this effect, even though the language does not explicitly include practice guidelines.¹⁹⁹ Physicians who treat Medicare patients "in compliance with or reliance upon professionally developed norms of care and treatment applied by "a peer review organization are protected from civil liability."²⁰⁰ However, in order to enjoy this protection, the physician must have "exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment."²⁰¹ A strong argument can be made that where a guideline applies to the clinical situation at issue and the physician follows it with the due care of a reasonably prudent physician in similar circumstances, then the statute could provide complete protection from malpractice liability.²⁰² This possibility has not yet been tested judicially. However, if a court regards a guideline as conclusive in such a case and finds that the physician departed from it, then the physician would have no opportunity to challenge the guideline itself.

¹⁹⁵ *Id.*

¹⁹⁶ *See id.*

¹⁹⁷ 169 F.3d 1287 (10th Cir. 1999) (adding that ERISA does not require that employers provide any particular benefits in a plan).

¹⁹⁸ *See id.*

¹⁹⁹ *See id.*

²⁰⁰ 42 U.S.C. § 1320c-6(c) (1994).

²⁰¹ 42 U.S.C. § 1320c-6(c)(2) (1994).

²⁰² *See Hirschfeld, supra* note 14, at 1562.

B. State Legislative Initiatives – The Maine Project

In the past decade, some states have begun to experiment with ways to integrate practice guidelines into cost-containment efforts and universal access to health care initiatives. In so doing, they have given guidelines the force of the law.

Maine initiated a pilot project in 1991 – the Maine Medical Liability Demonstration Project (Maine Project) – that legislatively created parameters in four specialties.²⁰³ In addition, in the early 1990s, President Clinton's health care proposals recommended procedural reforms for medical malpractice litigation, specifically adopting programs such as the one in "Maine that frees doctors from malpractice liability if they can demonstrate that they followed prescribed clinical practice guidelines."²⁰⁴ The Maine Project provided an affirmative defense in malpractice actions for physicians who complied with the guidelines.²⁰⁵ However, plaintiffs were not allowed to use them to prove negligence if a physician decided not to follow them in the first place.²⁰⁶ Specifically, the legislation provided:

In any claim for professional negligence against a physician or the employer of a physician . . . in which a violation of a standard of care is alleged, *only the physician or the physician's employer may introduce into evidence, as an affirmative defense*, the existence of the practice parameters and risk management protocols developed and adopted pursuant to § 2973 for that medical specialty area.²⁰⁷ . . . Any physician or physician's employer who pleads compliance with the practice parameters . . . as an affirmative defense to a claim for professional negligence has the burden of proving that

²⁰³ See ME. REV. STAT. ANN. tit. 24, §§ 2971-78 (West Supp. 1998) (indicating that the project would run from Jan. 1, 1992 to Dec. 31, 1999).

²⁰⁴ WHITE HOUSE DOMESTIC POLICY COUNCIL, THE PRESIDENT'S HEALTH SECURITY PLAN § 1 at 91 (1993) (explaining President Clinton's 1993 health care reform proposals).

²⁰⁵ See ME. REV. STAT. ANN. tit. 24, § 2975(1)-(2) (West Supp. 1999).

²⁰⁶ See Crane, *supra* note 22, at 243 (discussing the Maine Project and its attempt to use practice parameters as the standards of care).

²⁰⁷ ME. REV. STAT. ANN. tit. 24, § 2975(1) (West Supp. 1998-99) (emphasis added).

the physician's conduct was consistent with those parameters²⁰⁸

The Maine legislature had two health care policy issues in mind when it developed the Project: (1) increased costs of insurance; and (2) the practice of "defensive medicine" to shield from liability physicians who comply with the parameters.²⁰⁹ Essentially, the Project was "an attempt to create legal incentive structures that make practice guidelines more appealing to physicians."²¹⁰

Three significant obstacles hindered the Maine Project. First, it was developed without regard to the State's mandatory pre-litigation screening panel for medical malpractice cases, which undermined the possibility of avoiding the lengthy procedures involved in defending a malpractice suit.²¹¹ Panels were to be comprised of a retired judge, an attorney, and a medical practitioner in the defendant's specialty.²¹² A unanimous finding by a panel of negligence was admissible in a subsequent jury trial, and a plaintiff was allowed to proceed to trial regardless of a panel's findings.²¹³ Therefore, the legislation did not preclude the possibility of lengthy litigation. Second, although it imposed the burden of proof on defendants, it denied plaintiffs the right to a jury trial and the use of evidence regarding guidelines.²¹⁴ Finally, the creation of the guidelines applied in the Project might not have been totally reliable. Advisory committees were established to develop the guidelines, appointed by the Maine Board of Registration in Medicine, the Governor, and leaders of the State Legislature, with the Maine Medical Association and

²⁰⁸ ME. REV. STAT. ANN. tit. 24, § 2975(2) (West Supp. 1998-99).

²⁰⁹ See Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 N.E. L. REV. 69, 78 (1995) (citing Gordon H. Smith, *A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine*, 19 JOINT COMM'N J. QUALITY IMPROVEMENT 356 (1993)).

²¹⁰ Matthews, *supra* note 1, at 277 (adding that the dissemination of guidelines has insufficiently changed practice patterns).

²¹¹ See Jennifer Begel, *supra* note 209, at 71 (1995) (describing obstacles in attempting to use physician practice guidelines in tort reform).

²¹² See ME. REV. STAT. ANN. tit. 24 § 2852(2) (West 1996 and Supp. 1998) (describing the formation and procedures of review panels).

²¹³ See Begel, *supra* note 209, at 74-75 (discussing the lack of impact of findings by pre-litigation screening panels).

²¹⁴ See *id.* at 71 (describing the Project's constitutional obstacles).

medical specialty societies serving in advisory roles.²¹⁵ However, it is unclear whether a process effectuated by state organizations would have promulgated guidelines reflecting national standards.

Eight years after the Project's commencement, not one plaintiff has initiated a lawsuit against a physician in which guidelines were a major issue in the case.²¹⁶ In addition, although plaintiffs' lawyers had threatened to challenge the Project's constitutionality, none did.²¹⁷ Furthermore, analogous pilots in Minnesota, Florida, and Vermont have been repealed or abandoned.²¹⁸ Although proponents of tort reform hoped that use of the Maine guidelines would lead to a reduction in the need to present expert testimony in court, this has not yet happened.²¹⁹ Instead, where guidelines themselves have become a significant issue in a case, the "battle of expert witnesses" persists.²²⁰

C. The Need for Consistency in Guidelines

As they currently exist, guidelines often depart substantially from generally accepted standards of practice.²²¹ According to the General Accounting Office (GAO), one insurance plan modified the CDC recommendation of chicken pox vaccines for all healthy children by suggesting that physicians discuss the level of immunity offered by the vaccine and then allow parents to decide whether they desire the vaccine for their own children.²²² The guideline also opines that it is preferable that children have chicken pox to assure lifetime immunity rather than receive the vaccine.²²³ In considering the potential impact of this plan's position, note that children can die from

²¹⁵ See ME. REV. STAT. ANN. tit. 24, § 2972(2)(A)-(D) (West Supp. 1998) (outlining the make-up of the medical specialty advisory committees).

²¹⁶ See Crane, *supra* note 22, at 243 (noting that the Project expired at the end of 1999).

²¹⁷ See *id.*

²¹⁸ See *id.*

²¹⁹ See *id.* at 236 (commenting that the battle of expert witnesses is more likely to escalate in litigation where the guidelines are a key issue).

²²⁰ *Id.*

²²¹ See ROSENBLATT, *supra* note 31, at 570.

²²² See Practice Guidelines: *Managed Care Plans Customize Guidelines to Meet Local Interests*, GAO-HEHS-96-95, May 30, 1996, at 11 (discussing the effects of local customization of published guidelines).

²²³ See *id.*

chicken pox complications, which is one of the reasons for the vaccine.²²⁴

Even where guidelines recommend essentially consistent approaches for a particular medical procedure, they often vary in level of detail. A comparison of two prostate cancer-screening guidelines illustrates this observation. One protocol enumerates five factors for physicians to consider in deciding which men are the most appropriate candidates for screening, including age and family history.²²⁵ It further lists eight warnings physicians should give to patients prior to testing, including the fact that the benefits of screening and aggressive treatment for prostate cancer have not been proven.²²⁶ However, another prostate cancer screening guideline simply states that routine screening is not necessary for all patients and that those requesting it should receive objective information about the benefits and harms.²²⁷ Furthermore, whereas one protocol suggests that men aged fifty to sixty-nine will enjoy the most benefit from screening, another encourages it for men aged fifty and older with a life expectancy of greater than ten years.²²⁸

These examples illustrate the reality that guidelines are not currently consistent enough in level of detail to warrant conclusive evidentiary weight. Some physicians might choose to use less detailed guidelines that allow more room for subjective medical judgment. Conversely, those providers who feel more comfortable relying on recommendations that contain more explicit detail may violate such guidelines with the same actions that would probably be permissible under looser guidelines.

VII. THE POTENTIAL FOR GUIDELINES TO IMPROVE THE PROCESS OF MALPRACTICE LITIGATION

If reliable practice guidelines become routinely available and a sufficient number of them are created so that there exist relevant guidelines for all medical instances, the legal system could efficiently and consistently base malpractice decisions on

²²⁴ See ROSENBLATT, *supra* note 31, at 570.

²²⁵ See National Guidelines Clearinghouse (visited July 14, 2000) <<http://www.guideline.gov>> [citations omitted].

²²⁶ See *id.*

²²⁷ See *id.*

²²⁸ See *id.*

them.²²⁹ As a result, the number of claims brought would eventually decrease because improved quality of care would reduce the need for suits in the first place.²³⁰

We know from industrial examples that building quality into the product is far preferable to postproduction inspection to identify products that are meeting standards. Malpractice claims are the ultimate inspection. They generate fear, manifested in defensive medicine, and offer few incentives to assure quality. Practice guidelines offer enormous potential to improve practice, to reduce avoidable bad outcomes and, possibly, eventually to reduce malpractice claims.²³¹

Furthermore, guidelines should provide enough specificity for physicians to follow them, but should also allow room for independent medical judgment. They should also be created with scientific objectivity and freedom from conflicts of interest.

A. Specificity of Guidelines and Allowing Room for Independent Judgment

Contrary to what opponents of the use of practice guidelines might believe, those who value them do not define the goal of relying on them as the elimination of all opportunities for professional discretion and judgment from the practice of medicine.²³² Instead, guidelines ideally serve the modest function of adding structure to the medical decision-making process. "Knowledge brings limitations, or, at least, the basis of limitations to be imposed."²³³ "[T]he creation of practice guidelines . . . can be seen as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment."²³⁴

²²⁹ See *id.*

²³⁰ See Robert H. Brook, *Practice Guidelines and Practicing Medicine: Are They Compatible?*, 262 JAMA 3027, 3030 (1989) (discussing the creation, adoption, and effect of clinical practice guidelines); see also Goldschmidt, *supra* note 132, at 2062.

²³¹ Goldschmidt, *supra* note 132, at 2062.

²³² See Rosoff, *supra* note 8, at 375 (discussing the ways in which clinical practice guidelines may be used in the managed care setting).

²³³ *Id.*

²³⁴ IOM II, *supra* note 5, at 2.

1. Degrees of Specificity

Assuming the incorporation of guidelines into the practice of medicine becomes more widely accepted, then the amount of breathing room physicians have in which to apply their own independent judgment will depend, in part, on the specificity of the protocols themselves. Thus, the critical question becomes how specific guidelines should be. The answer to this question will have a profound impact on the validity and integrity of guidelines as they are used by both the medical and legal professions.

To be medically efficacious, practice guidelines must be specific enough, as discussed *supra*, to provide meaningful guidance upon which physicians can consistently rely. However, blind reliance on formulaic standards poses the threat of hampering the use of medical judgment in subjective cases. To be useful in a legal context, guidelines must be specific enough to provide clear standards against which to measure a defending physician's behavior. Although vague standards serve little evidentiary value, inflexible standards may adversely implicate physicians who appropriately invoked experience and intelligence and who meticulously considered the facts of an individual patient's case in making difficult clinical decisions.

Attorneys are well aware of this paradox. According to one defense attorney, "[i]f they are to represent the 'standard of care,' then any deviation is a problem. If they don't represent the 'standard of care,' then even if a doctor complies, he could still be negligent."²³⁵ A plaintiff's attorney articulated the other side of this conflict – "guidelines usually do not contain definitive statements of what is required to constitute appropriate care, thereby allowing the health care provider to wiggle out of an apparent violation."²³⁶

2. The Need for Independent Judgment

No single set of guidelines can account for every variable that affects the diagnosis and treatment of a given patient. First, guidelines often respond to specific situations only contemplated in controlled experimental environments. For example,

²³⁵ Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289, 304-05 (1996) (discussing how attorneys view the use of guidelines).

²³⁶ *Id.* at 304.

protocols created to counsel intraoperative monitoring by anesthesiologists have been proven to decrease morbidity and mortality, but these guidelines address highly specific aspects of care in fixed environments.²³⁷ Second, specific conditions seldom occur as isolated ailments. Rather, they often involve multiple organ system interactions and dysfunctions.²³⁸ Furthermore, a treatment that might be effective for a particular condition that exists in isolation may actually adversely affect other dysfunctions or disease processes.²³⁹ Only a physician's trained eyes, ears, and mind can reconcile the multitude of factors that interact in a given clinical situation. Guidelines can merely supplement a physician's judgment and should not attempt to provide a substitute. A realistic goal for guidelines may be that they cover eighty percent of the cases.²⁴⁰

In a Western culture approaching the 21st Century, sophisticated technology has enabled the development of medical equipment and instruments and computer-generated research data that have made many procedures possible and have improved the consistency and predictability of successful outcomes. However, the gift of modern technology and research can not replace, and, in fact, depends upon, independent medical judgment. Although the ability to challenge guidelines themselves in light of *The H.J. Hooper's* legacy addresses this concern, explored *supra*, it remains important to allow room for independent medical judgment. A profession that has raised the bar for medical school admissions, residency placements, and board certification must continue to harvest the skills and intellects that its elite members contribute.

"Part of good science is clarifying where evidence ends and opinion begins."²⁴¹ As discussed *supra*, good guidelines should specify which of the medical recommendations contained therein have been proven and which aspects of the screening, diagnosis, or treatment remain uncertain. Because formal scien-

²³⁷ See John D. Ayers, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421, 427 (1994) (citing Ellison C. Pierce, *The Development of Anesthesia Guidelines and Standards*, 16 QUALITY REV. BULL. 61 (1990)).

²³⁸ See *id.* at 428 (citing David M. Eddy, *The Individual vs. Society: Is There A Conflict?*, 265 JAMA 1446 (1991)).

²³⁹ See *id.* (citing *Problems in Managing Coexisting Cardiovascular, Renal Disease*, INTERNAL MED. NEWS, June 15, 1991, at 1, 44).

²⁴⁰ Telephone Interview with Brad Moore, *supra* note 130.

²⁴¹ Woolf, *supra* note 105, at 167S (showing that good practice guidelines will clarify what has been proven by scientific studies).

tific research cannot always suffice to ascertain what is in a patient's best medical interests, expert opinion and first-hand experience play valuable roles in filling the crucial gap between what a guideline covers and what requires independent medical judgment.²⁴²

Individual variation characterizes clinical practice, and insurance clauses about medical necessity demand flexibility that accounts for a patient's individual needs.²⁴³ "Given the enormous number of procedures and the individual circumstances of patients, limiting insurance coverage to a host of separately validated and specifically described procedures is impractical."²⁴⁴ Guidelines should be treated as additions to the pool of data available to the medical profession to solve questions of resource utilization, and as guides for individual practitioners in the day-to-day decision making process, rather than as the basis for a per se standard of care in utilization or quality assurance conflicts.²⁴⁵ It follows that no single practice guideline for a particular condition can suffice as conclusive evidence.

Some guidelines have acknowledged the importance of relying on independent medical judgment. For example, the actuarial firm Milliman & Robertson Co. has prepared a guideline for ambulatory care, which notes "[t]he guidelines should be applied to establish a course of treatment for a specific individual only in conjunction with the application of professional medical judgment"²⁴⁶ If adopted as rigid legal standards, failure to heed a practice guideline could guarantee defeat for defending physicians.²⁴⁷

B. The Impact of Conflicts of Interest on Reliability

Not only must guidelines be derived from objective research, but their reliability depends on freedom from conflicts of interest.

²⁴² See *id.* at 167S-68S (citing D.M. Berwick, *Harvesting Knowledge From Improvement*, 275 JAMA 877-78 (1996)).

²⁴³ See Rosenbaum, *supra* note 18, at 230.

²⁴⁴ *Id.* at 231.

²⁴⁵ See Ayres, *supra* note 237, at 423 (arguing against certain types of guidelines).

²⁴⁶ MILLIMAN & ROBERTSON, *HEALTH CARE MANAGEMENT GUIDELINES*, VOL. 3: *AMBULATORY CARE GUIDELINES*, 1.1 (1995).

²⁴⁷ See Hirshfeld, *supra* note 14, at 1560 (explaining difficulties doctors might face if plaintiffs use parameters in court).

The sine qua non of scientific research is the production of objective results, and objectivity is ensured through a process of open and vigorous debate among persons who have no financial stake in the outcome. Yet much of the decision making about insurance coverage is based on unpublished, proprietary, and unreviewed data. Furthermore, methods are undisclosed and unexamined unless litigation ensues. *An endeavor that operates in this fashion and is subject to the conflict of interest inherent in the insurance industry cannot justifiably be called scientific.*²⁴⁸

Moreover, studies indicate that practice guidelines often rely on insurance company decisions rather than on scientific research.²⁴⁹ This presents another reason a guideline must reflect a carefully conducted and nationally relevant consensus.

Whereas from the 1950s to the 1970s physicians made coverage decisions that went largely unchallenged by insurers, physician autonomy is a relic of the past.²⁵⁰ In a managed care environment, insurers have usurped the power to make coverage determinations, which inherently allows them to ordain professional standards of care.²⁵¹ One bill introduced in the U.S. Senate would have required that medical necessity standards employed by insurers reflect "generally accepted principles of professional medical practice."²⁵² In addition, it would have required insurers to provide external reviewers to consider, *inter alia*, the patient's medical information, the treating physician's opinion, and that practice guidelines substantiated by government-financed research and those developed by insurers be declared "free of any conflict of interest."²⁵³ Although the bill did not become law, similar legislation will likely be introduced in the next session of Congress.²⁵⁴ In the meantime, the need to develop objective and conflict-free guidelines is unquestionable.

²⁴⁸ Rosenbaum, *supra* note 18, at 231 (emphasis added).

²⁴⁹ See *id.* (citing as an example MILLIMAN & ROBERTSON HEALTHCARE MANAGEMENT GUIDELINES, 1996-98).

²⁵⁰ See *id.* at 229.

²⁵¹ See *id.*

²⁵² *Id.* (quoting S. 2416 (105th Cong.) §§ 102(b)(1), (4), 106(b)(3) (1998)).

²⁵³ *Id.*

²⁵⁴ See Rosenbaum, *supra* note 18, at 229.

One case decided by a federal court illustrates the problems insurers face when they rely on internal guidelines both in making coverage determinations and in litigating subsequent problems. In *Adams v. Blue Cross/Blue Shield of Maryland, Inc.*,²⁵⁵ the U.S. District Court for the District of Maryland held that the defendant plan improperly denied coverage of HDC-ABMT.²⁵⁶ The plan's corporate medical director had formulated plan guidelines that considered the treatment to be experimental based on a technology evaluation of the treatment conducted by the Blue Cross National Association.²⁵⁷ The court ruled that the medical director acted improperly by failing to base its coverage policy for the cancer treatment on a consensus of Maryland oncologists and the plaintiff's treating physicians, but instead relied on outside scientific opinion and his own review of the literature.²⁵⁸ Although the "tech committee" was probably comprised of highly qualified scientists who based the guidelines on rigorous medical research, the fact that they were employed directly by the plan raises the question of their impartiality.

VIII. RECOGNIZING BIAS IN THE UTILITY OF GUIDELINES FOR OFFENSIVE AND DEFENSIVE PURPOSES

Regardless of whether guidelines eventually constitute conclusive evidence of the applicable standard of care in malpractice cases, the future of guideline use for litigation purposes may be asymmetrical.²⁵⁹ The degree to which guidelines should be regarded as conclusive evidence of the standard of care may depend on whether courts are skewed in accepting them for inculpatory or exculpatory purposes. The controversy surrounding the Maine Project, discussed *supra* section VI.B., illustrates the problems that can arise when legislatures make value judgments as to whether physicians can escape personal liability when they follow guidelines, regardless of the independent judgment exercised.

Andrew Hyams conducted a survey of reported cases from 1980 through 1994 to ascertain whether plaintiffs or defendants

²⁵⁵ 757 Supp. 661 (D. Md. 1991).

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 665.

²⁵⁸ *Id.* at 676.

²⁵⁹ See Rosoff, *supra* note 8, at 388 (evaluating the use of clinical practice guidelines in both offensive and defensive contexts).

have been more successful in using guidelines.²⁶⁰ The study reveals that plaintiffs have used them with a substantially higher degree of success than defendants.²⁶¹ The following are examples of cases evaluated that illustrate how the evidentiary role of guidelines plays out in both offensive and defensive contexts.

A. Inculpatory Guidelines

In the cases where plaintiffs have used them effectively for inculpatory purposes, guidelines helped these parties to oppose summary judgment motions or to prevail on motions for judgment as a matter of law.²⁶² One example is *James v. Woolley*, in which the Alabama Supreme Court reversed a summary judgment decision granted in favor of the defendants in a malpractice action brought to recover for the paralysis of a newborn's arm as a result of delivery.²⁶³ The court found persuasive the deposition testimony of an expert who relied on an American College of Obstetrics and Gynecology (ACOG) technical bulletin that advised a cesarean section in any situation where a woman with gestational diabetes gives birth to a baby weighing over 4000 grams.²⁶⁴ Because the plaintiff, as the non-moving party, presented evidence from which an inference could be drawn to support his claim, the appellate court remanded the case so a jury could weigh the material issues of fact.²⁶⁵

In *Washington v. Washington Hospital Center*,²⁶⁶ the District of Columbia Court of Appeals partially relied on the plaintiff's proffer of guidelines promulgated by the American Association of Anesthesiology (AAA) in ascertaining the standard of care in a case brought on behalf of a woman who suffered catastrophic brain injury.²⁶⁷ In doing so, the court rejected the defendant's argument that the AAA Standards for Basic Intra-Operative Monitoring, which "encouraged" the use of carbon

²⁶⁰ See Hyams et al., *supra* note 235, at 295 (discussing a computerized legal research study performed by the Authors to assess use and performance of medical malpractice guidelines in the United States).

²⁶¹ See *id.* at 295-96.

²⁶² See *id.* at 296.

²⁶³ 523 So. 2d 110, 112-13 (Ala. 1988) (finding an issue of material fact as to the physician's negligence).

²⁶⁴ See *id.*

²⁶⁵ See *id.* at 113.

²⁶⁶ 579 A.2d 177 (D.C. App. 1990) (describing a case in which a family sued on behalf of a patient in a persistent vegetative state).

²⁶⁷ *Id.* at 182.

dioxide monitors, were merely "emerging" recommendations that were not "mandatory."²⁶⁸ According to the court's reasoning, "[a] standard of due care . . . necessarily embodies what a *reasonably prudent* hospital would do . . . and hence care and foresight exceeding the minimum required by law or mandatory professional regulation may be necessary to meet that standard," and guidelines and supporting medical journal articles that deem a standard as emerging can have a "bearing" on an expert's opinion testimony.²⁶⁹ This case elucidates the challenges guideline drafters face when they attempt to couch directions or recommendations in tentative language intended to prevent plaintiffs from using guidelines offensively.²⁷⁰ It also demonstrates the inherent limitations plaintiffs face when a court can only accept guidelines as persuasive when presented via expert testimony, but not as independent exhibits.

B. Exculpatory Guidelines

Guidelines have also inured to the benefit of physicians defending malpractice suits. *Levine v. Rosen*²⁷¹ is an example of a case in which a defendant successfully employed guidelines for exculpatory purposes. In a case against a physician for failure to diagnose breast cancer, Mrs. Levine visited her physician to examine apparent abnormalities on her breast,²⁷² but Dr. Rosen did not deem it necessary to order any diagnostic tests. However, a subsequent mammogram revealed adenocarcinoma.²⁷³ The defendant submitted into evidence ACOG guidelines recommending "regular" mammography within the treating physician's discretion to refute American Cancer Society recommendations of annual mammograms for women over the age of fifty.²⁷⁴ The appellate court remanded the case and suggested that the trial court instruct the jury clearly on the "two schools

²⁶⁸ See *id.* (explaining that plaintiff's expert witness partially relied on practice guidelines in giving testimony on the use of end-tidal carbon dioxide monitors).

²⁶⁹ *Id.* (emphasis in original).

²⁷⁰ See Hyams et al., *supra* note 235, at 299 (discussing use of inculpatory guidelines).

²⁷¹ 616 A.2d 623 (Pa.1992) (holding that clinical guidelines may be used under a "two schools of thought" doctrine).

²⁷² See *id.*

²⁷³ See *id.* at 625 (adding that the patient subsequently underwent a right modified radical mastectomy and chemotherapy).

²⁷⁴ See *id.* at 625-26.

of thought" doctrine and explain that it does not shield a doctor from liability for failure to recognize symptoms.²⁷⁵

*Quigley v. Jobe*²⁷⁶ is an example of a case where a court rejected guidelines in favor of the defendant. The trial court refused to admit risk-management guidelines submitted by the plaintiff that were generated by an insurance company and recommended a follow-up exam for breast carcinoma within a specified period of time.²⁷⁷ The court of appeals ruled that the trial court did not abuse its discretion in reasoning that "the guidelines were not relevant because they were promulgated by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession."²⁷⁸ Furthermore, the trial court had excluded the guidelines because the prejudicial effect of introducing evidence of the defendant's insurance coverage would have outweighed the probative value of the guidelines.²⁷⁹

IX. CONCLUSION – WHERE DO WE GO FROM HERE?

Guidelines should never be deemed dispositive as the applicable standard of care applied in a malpractice action. Both the medical and legal professions are far from witnessing the day when guidelines can be conclusive and where following them diligently would preclude further inquiry into a physician's conduct. However, the Tenth Circuit's shocking decision in *Jones v. Kodak* to uphold a health plan's benefit denial based on guidelines by insulating that plan from having to disclose its guidelines in the first place raises disturbing questions about the future of guidelines. Perhaps some courts are closer than they should be in blindly accepting guidelines without examining their relevance or reliability. "Rather, [other] individual courts

²⁷⁵ *Id.* at 628 (noting that upon retrial, the judge should specify on which allegation of negligence there were "two schools of thought").

²⁷⁶ 851 P.2d. 236 (Colo. App. 1992) (holding that the trial court did not abuse its discretion in deciding that risk management "guidelines were not relevant because they were promulgated by a private insurance company . . . [and they are not a] recognized standard of care within the medical profession").

²⁷⁷ *Id.* at 238 (holding that risk management guidelines contained in a professional liability policy were not applicable as a relevant standard of care within the medical profession).

²⁷⁸ *Id.*

²⁷⁹ *See id.*

will continue to balance the rights of individuals against the needs of society at large in a case-by-case basis"²⁸⁰

Harold C. Sox, outgoing president of the American College of Physicians-American Society of Internal Medicine, opines that guidelines will increasingly be viewed as the standard of care and will actually help in defending physicians.²⁸¹ "In a just and rational world, physicians who follow peer reviewed professional guidelines will be held blameless when a patient has bad luck I'm not aware of a situation where a physician followed such a guideline appropriately and lost the case."²⁸² As guidelines become more widely accepted as the standard of care, prudent physicians will have no choice but to be aware of them. "Imagine being on the witness stand and testifying that you don't know what your specialty society recommends . . . [.]"²⁸³

The reality that guidelines will inevitably be afforded increasing evidentiary weight over the coming years is not objectionable. However, we are far from ready for courts to deem guidelines conclusive without first establishing a nationally appropriate measure of their validity. Until guidelines become more standardized and reliable according to objective and nationally recognized standards, due process concerns should prohibit judicial inquiry from ceasing after the question of whether a defendant obeyed a particular guideline is addressed. Rather, both parties should be afforded the due process of claiming adherence to or departure from the standards, or of challenging the standards themselves. Perhaps the puzzle over the definition of the medical profession epitomizes the debate over the appropriate use of practice guidelines: "Is medicine a science or an art?"²⁸⁴ Accepting the theory that it should be considered both leads to the inevitable conclusion that guidelines cannot be deemed conclusive without stripping the medical profession of its autonomy.

²⁸⁰ Matthews, *supra* note 1, at 299 (implying that guidelines may encourage dialogue between technocratic devotees and legal and medical critics).

²⁸¹ Crane, *supra* note 22, at 239 (discussing ideas of Harold C. Sox, who believes physicians will effectively write guidelines to avoid litigation).

²⁸² *Id.*

²⁸³ *Id.* at 243 (quoting practitioner Gil Solomon, M.D.).

²⁸⁴ See Matthews, *supra* note 1, at 275 (noting how ambiguity in self-definition has historically plagued medical professionals).

